

NOTICE

Synthetic Analogue of the F3 Fraction of Feline Facial Pheromone

in the product:

FELIWAY DIFFUSER: ANALOGUE OF FELINE FACIAL PHEROMONE

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Virbac (Australia) Pty. Limited for registration of a new product containing the new active constituent *Synthetic Analogue of the F3 Fraction of Feline Facial Pheromone* ('the active constituent'). The product is FELIWAY DIFFUSER: ANALOGUE OF FELINE FACIAL PHEROMONE ('the product'). The product is for use in cats.

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the APVMA should grant the application for approval of the active constituent and registration of the product. Submissions should state the grounds on which they are based. Such grounds should relate only to matters outlined below that the APVMA is required to take into account in deciding whether to grant the application. The APVMA must receive comments within 28 days of the date of this notice.

Particulars of the Application

Proposed product name:	FELIWAY DIFFUSER: ANALOGUE OF FELINE FACIAL PHEROMONE
Applicant company:	Virbac (Australia) Pty. Limited
Name of active constituent:	<i>Synthetic Analogue of the F3 Fraction of Feline Facial Pheromone</i>
Signal heading:	Unscheduled
Statement of claims:	Aids in alleviating signs associated with fear and stress in kittens and cats.
Pack sizes:	Diffuser and 48mL refill
Withholding period:	Not applicable

Summary of the APVMA's evaluation of *Synthetic Analogue of the F3 Fraction of Feline Facial Pheromone* in FELIWAY DIFFUSER: ANALOGUE OF FELINE FACIAL PHEROMONE in accordance with Section 14(3)(e) and (f) of the Agricultural and Veterinary Chemicals Code (the 'Agvet Code'), scheduled to the Agricultural and Veterinary Chemicals Code Act 1994

The APVMA has evaluated the application and in its assessment in relation to human and environmental safety under section 14(3)(e) of the Agvet Code, proposes to determine that:

- (i) The APVMA is satisfied that the proposed use of the active constituent in the product would not be an undue hazard to the safety of people exposed to it during its handling and use.

The Office of Chemical Safety (OCS) in the Commonwealth Department of Health and Aging assessed the human toxicological aspects of this application. The product is a mixture of fatty acid methyl esters which act conjointly as an analogue of a naturally occurring feline pheromone when released into an indoor environment using an electrical diffuser supplied as part of the product. The product will be formulated in France.

The OCS advised the APVMA that use of the product would not be an undue hazard to the safety of people exposed to it during its handling and use and therefore recommended no safety directions. The APVMA accepts the findings and recommendations of OCS on this criterion.

- (ii) The APVMA is satisfied that the proposed use of the active constituent in the product will not be an undue hazard to the safety of people using anything containing its residues. The product is used indoors for cats and kittens and the active constituent is unlikely to enter the human food chain.
- (iii) The APVMA is satisfied that the proposed use of the active constituent in the product is not likely to be harmful to human beings if used according to the product label directions.

The active constituent is a mixture of fatty acid methyl esters which act conjointly as a naturally occurring feline pheromone. The National Drugs and Poisons Scheduling Committee (NDPSC) has examined the active constituent and placed it in Appendix B (substances considered not to require control by scheduling), of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). The active constituent is therefore unclassified. The appropriate Signal Heading is on the product label.

The OCS has not recommended First Aid and Safety Directions for the product. The product is screwed to a diffuser which is then plugged into an electric socket. The electrically-heated diffuser which is to be placed in the room most often used by the cat, evaporates the liquid from the vial. The OCS considered that because exposure under these circumstances is likely to be minimal and the acute toxicity of the product is low, no hazard-based safety directions need be recommended. The diffuser itself complies with relevant sections of the Australian and New Zealand Standards 3100:2002 and 3112:2000 as amended.

The APVMA accepts the findings and recommendations of OCS on this criterion.

- (iv) The APVMA is satisfied that the proposed use of the active constituent in the product in cats is not likely to have an unintended effect that is harmful to animals, plants or the environment. The active constituent is an analogue of a naturally occurring pheromone. When used as directed on the label, the Department of the Environment and Water Resources (DEW) noted the lack of adverse effects and low risk to the environment associated with the indoor pattern of use.
- (v) The APVMA is satisfied that the proposed use of the active constituent in the product would not adversely affect trade between Australia and places outside Australia because the product is used in cats.

In relation to its assessment of efficacy under section 14(3)(f), the APVMA proposes to determine that:

- (i) The APVMA is satisfied the data from trials and extensive use under Permit supporting the efficacy of the product adequately demonstrate that under local conditions this product is effective for the proposed uses.

Written submissions on the APVMA's proposal to grant the application for registration should be addressed to:

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